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## POLICY AND PROCEDURES

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### Office of Management

#### CDER Full-Time Equivalent (FTE) Ceiling and Onboard Tracking and Reporting

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#### PURPOSE

This MAPP describes the process for collecting, tracking, and reporting onboard FTEs and ceiling totals within the Center for Drug Evaluation and Research (CDER).

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#### BACKGROUND

The objective of tracking FTE gains, losses, and ceiling adjustments, including FTE transfers between offices, is to provide senior management with the most reliable data for determining current and future FTE resource allocation needs and to ensure the Center is operating within the ceiling limit established by FDA.

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#### POLICY

- FTE ceiling allocations for each office are determined by the Center Director.
- FTE ceilings dictate the maximum number of FTEs an office may maintain without prior approval from the Center Director.
- The classification of an FTE, i.e., Salary & Expenses (S&E), Prescription Drug User Fee Act (PDUFA), Generic Drug User Fee Act (GDUFA), or Biosimilar User Fee Act (BsUFA), is determined by the Program and Resource Management Branch (PRMB), Office of Management (OM). The status of an FTE transferred from one office to another within CDER is determined by the 'sending' office.

- FTE ceiling adjustments must be approved by the Director, CDER or the Director, OM, after review by the CDER Financial Council (see MAPP 4658.3).
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## RESPONSIBILITIES

### **Management Officer or Program Specialist, if delegated, of each office will:**

- Provide the Management Analysis Branch (MAB), Division of Management and Budget (DMB) with staffing gains and losses for designated pay periods.
- Provide MAB with ceiling adjustments when approved by the Director, CDER or the Director, OM.
- Update MAB when there are changes to employee status, e.g., name changes, Entry on Duty (EOD) date changes, student status.
- Notify DMB when there are changes to an FTE's classification (e.g., from GDUFA to PDUFA).
- Provide DMB with an updated Table of Organization (TOO) each month, reflecting current staffing, flagging all GDUFA employees, and identifying any known EODs and/or students.

### **The Division of Management Services (DMS), OM, will:**

- Provide MAB with Center Gains and Losses reports and projected EOD lists at least once a month, as well as an updated student list as appropriate.

### **The Program and Resource Management Branch (PRMB), Division of Management and Budget (DMB), OM, will:**

- Verify ceiling adjustments and FTE classifications (S&E, PDUFA, GDUFA, and BsUFA).
- Notify MAB when ceilings or classifications are changed.

### **The Management Analysis Branch (MAB) will:**

- Email MOs a request for staffing gains and losses every two weeks.
  - Collect, maintain, and track gains and losses data from various sources, including Business Objects, MOs, DFAS, employee exit and new account emails, and DMS.
  - Communicate with MOs as needed to verify employee status.
  - Track Center ceiling adjustments and verify FTE classifications.
  - Create charts at the end of each month with updated ceiling and onboard data.
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## PROCEDURES

### **The Management Analysis Branch (MAB) will:**

- Download data from the Reporting and Analysis Module (RAM) in Business Objects on a monthly basis.

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- Compare RAM data with data received from other sources and consult with MOs if there are discrepancies.
  - If ceiling adjustments are made at the office level, consult with the Program and Resource Management Branch (PRMB) to identify FTE classification.
  - Revise CDER charts with updated ceiling adjustments and onboard counts. Add footnote(s) to reflect current change(s).
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## REFERENCES

Current and past information about the Prescription Drug User Fee Act, Generic Drug User Fee Act, and Biosimilar User Fee Act is available at:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee>

<http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees>

<http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA>

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## DEFINITIONS

- **CDER FTE Ceiling and FTE Onboard plus EOD Chart:** This monthly chart consolidates ceiling and current FTE numbers to determine the ceiling status for each office. Current month ceiling adjustments are footnoted.
- **CDER FTE Ceiling Split Chart:** This chart reflects current FTE ceilings for each office. All current fiscal year ceiling adjustments are footnoted.
- **Ceiling:** An office's authorized hiring limit established by the Center Director. This is the maximum number of FTEs an office is permitted to maintain. FTEs are classified as S&E, PDUFA, GDUFA, or BsUFA.
- **Entry On Duty (EOD) Date:** The date on which a new hire is expected to begin work.
- **Full Time Equivalent (FTE):** Those employees whose position counts towards an authorized hiring ceiling. An FTE may be one full time employee working 80 hours a pay period, or more than one part time employee whose combined hours worked total 80 hours a pay period. An FTE classification distinguishes career employees from non-career employees, such as contractors and students.
- **Students/Interns (Pathways Program):** Non-career employees typically working on intermittent schedules during the school year.
- **Table of Organization (TOO):** Super-office staffing spreadsheet maintained by Management Officers and forwarded monthly to the Management Analysis Branch.

**MANUAL OF POLICIES AND PROCEDURES**

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**MAPP 4658.1 Rev. 1**

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**EFFECTIVE DATE**

This MAPP is effective upon date of publication.

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**CHANGE CONTROL TABLE**

Effective Date	Revision Number	Revisions
09/05/2013	1	Updated to reflect GDUFA and BsUFA; Reference MAPP 4658.3 ( <i>Requesting New Full-Time Equivalents</i> )